REMARKS/ARGUMENTS

Claims 1-16 are active in this application with the amendments submitted for clarity and as such the rejections noted under 112, 2nd ¶ (pages 2-3 of the Action) are no longer applicable.

Claims 13-16 find support on page 24, lines 28-30; page 25, line 10, and page 26, line 10-12.

No new matter is added.

Applicants thank Examiner Westerberg for the courtesy of discussing this case with their undersigned representative on July 8, 2008. The substance of this discussion is summarized and expanded upon in the remarks below.

The pending claims in this application are directed to a multilayer dosage form of a pharmaceutical which includes a neutral core, an inner layer composed of a methacrylate polymer which itself is composed of particular (meth)acrylate monomers having particular properties, a specified outer core, and an active bound to the polymer of the inner core. As discussed in the application in the paragraph bridging pages 5-6, this formulation provided initial slow release (due to the outer layer) followed by a similar slow release of the active that was not affected by the ionic strength of the dissolution medium.

Even in view of WO 01/68767 (see pages 4-5 of the specification) that the claimed formulation provided these advantages was not predictable. Further, the Examples, particularly Examples 5 and 6, demonstrate that inner layers of particular types of polymer (Eudragit® RL 30D-having less than 90% by weight (meth)acrylate monomers) exhibit significantly different release rates under different ionic strengths unlike Eudragit® NE30 D-both of which are described in the Ulmius patent cited in the rejections.

Further, as also discussed in the specification on page 5, the inventors discovered that when inner methacrylate copolymer coating comprises at least 90% by weight of (meth)acrylate monomers having neutral radicals, wherein the methacrylate copolymer has a minimum film-forming temperature as specified in DIN 53 787 not exceeding 30°C, it is possible the active can be provided in the inner coating without the aid of excipients such as plasticizers or release agents as is typically the case in such formulations (see again WO 01/68767 and also the cited Ulmius patent; and new Claims 13-16).

To the rejection, Ulmius describes a multilayer drug delivery unit (see col. 5, lines 3-26) including any number of polymers, including Eudragit®-type polymers (see also the Examples). Col. 5 of Ulmius describes a first layer including many different types of polymers, including Eudragit® type polymers but none of the Examples in Ulmius describe polymers in the inner coat (or layer) that includes a polymer like that which is claimed). While the Examples use some of those Eudragit® polymers as the outer layer, the Examiner has determined that it would have been obvious to use any one of the Eudragit® polymers as an inner (or first) layer replacing the ethylcellulose (Aquacoat ECD30 is an aqueous dispersion of ethylcellulose[1]) as actually used by Ulmius.

Applicants disagree.

First, there is nothing in Ulmius which provides the necessary direction to specifically select the type of metacrylate polymer defined in the claims from amongst all the possible polymers that are described by Ulmius (see listing in col. 5, for example). Second, that the selection of the specific methacrylate polymer permitted slow release of the active that was not affected by the ionic strength of the dissolution medium (see Examples in the application) could not have been predicted based on what Ulmius described (see page 5, last ¶ of the present application).

[1] See, e.g., www.fmcbiopolymer.com/pharmaceutical/Products/Aquacoat.

Examples 5 and 6 illustrate the point made above. That is Example 5 employs Eudragit® NE 30 D as inner coat (that is meeting the definition provided in the claims) with an outer gastroresistant coating (Eudragit® L 30 D) whereas Example 6 uses an inner coat polymer Eudragit RL 30D, that is also described in Ulmius as a preferred polymer, see col. 5 and which does not meet the definition in the claims and having the same outer, gastroresistant coating (see page 33 of the specification). The release profiles of these two Examples are shown in FIGs 5 and 6 (reproduced below) with FIG 5 showing the release profile of Example 5 in different ionic medium, isotonic or hypotonic and FIG 6 showing the same analysis for the material in Example 6.

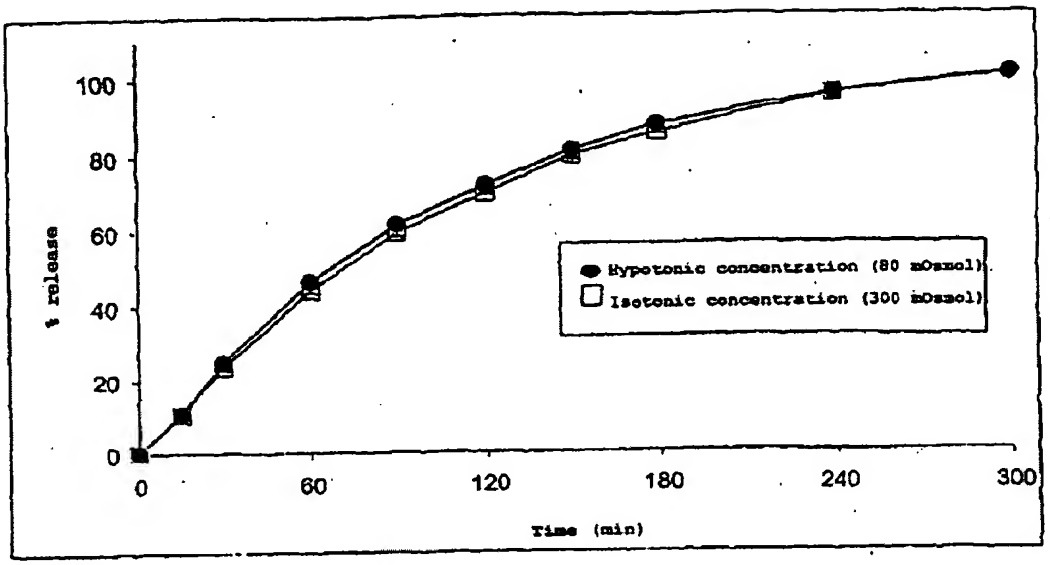

Fig. 5

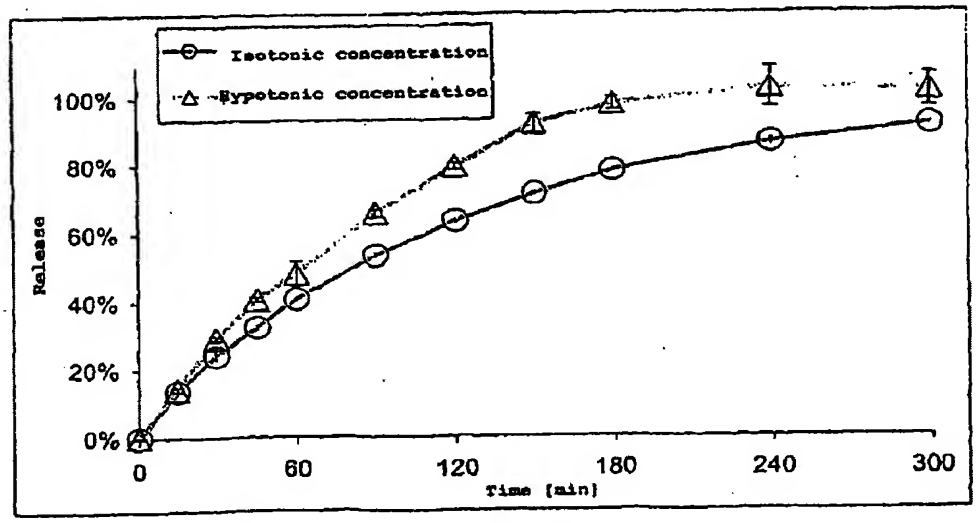

Fig. 6

As is clear from the figures, when the composition as defined in the claims was tested, the release profile remained relatively unchanged in the different ionic conditions, which was not the case for the composition in Example 6. Such an effect could not have been predicted based on what Ulmius described (see page 5, last ¶ of the present application).

Still further, with respect to new claims 13-16, the selection of the specific methacrylate polymer enabled the active to be provided in the inner coating without the aid of excipients such as plasticizers or release agents as is typically the case in such formulations (see pages 4-5 in the specification citing to WO 01/68767, also the cited Ulmius patent. This is not at all suggested by Ulmius.

Withdrawal of the rejection based on Ulmius is requested.

The Examiner has also rejected Claims 1-9 and 12 as being obvious in view of Ulmius combined with Beckert et al (WO 01/68058). Briefly, this rejection was raised primarily because Ulmius only describes glucocorticosteroids as the active and it for this that Beckert et al is cited. While Beckert does describe polymer coatings, e.g., methacrylate type polymers for the outer coating, Beckert does not alter the fact that what is described in Ulmius does not render the claims obvious and as a result the combination of the cited publications does not as well.

Withdrawal of the rejection is requested.

A Notice of Allowance is also requested.

Respectfully submitted,

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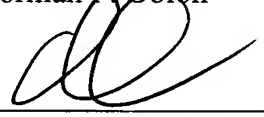
Norman F. Oblon



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